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September 20, 2005

**Via Electronic Mail**

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: FDA Docket No. 2004P-0223  
Whole Grain Descriptive Claim Citizen Petition Submitted on  
Behalf of General Mills, Inc.**

Dear Sir or Madam:

The Kellogg Company (Kellogg) respectfully submits these comments on the Whole Grain Descriptive Claims Citizen Petition filed by General Mills, Inc. (GM) on May 11, 2004.<sup>1</sup> This petition raises significant issues relating to effective communication of important health and dietary information that should be carefully considered by the Food and Drug Administration.

*SUMMARY OF KELLOGG POSITION*

As fully discussed in the GM petition, whole grains have been shown to reduce the risk of heart disease and certain cancers, as well as help reduce the risk of developing obesity and diabetes.<sup>2</sup> Accordingly, Kellogg's agrees that defining whole grain content terms will encourage consumption of this valuable food constituent, eliminate consumer confusion, and provide an inducement to food manufacturers to use more whole grains in their products. However, the definitions of terms relating to whole grain content proposed by GM will actually inhibit, rather than support, these important goals. Kellogg also believes that effective communication of whole grain information requires coordination with other governmental efforts to communicate important nutrition and dietary information, including the Dietary Guidelines 2005 and Food Guide Pyramid, both of which have been issued by the U.S. Department of Agriculture since the GM petition was filed.

With projected annual sales of more than \$9 billion, Kellogg is the world's leading producer of cereal and a leading producer of convenience foods, including cookies, crackers,

<sup>1</sup> Citizen Petition on Whole Grain Descriptive Claims, submitted by Stuart M. Pape of Patton Boggs LLP on behalf of General Mills, Inc., FDA Docket No. 2004P-0223, *available at*, <http://www.fda.gov/ohrms/dockets/dailys/04/may04/051204/04p-0223-cp000001-01-vol1.pdf>.

<sup>2</sup> Consumer Health Information for Better Nutrition (CHIBN) Task Force (July 10, 2003).

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toaster pastries, cereal bars, frozen waffles, meat alternatives, pie crusts and cones. The company's brands include KELLOGG'S®, KEEBLER®, KASHI®, NUTRI-GRAIN®, SPECIAL K®, EGGO®, MORNINGSTAR FARMS® and POP-TARTS®. Many of our products contain whole grains. Our comments below are part of our continuing efforts to promote healthy lifestyles and good nutrition in a range of products that consumers will purchase, not only for their nutritional and dietary value, but, also, for their good taste.

### *KELLOGG COMMENTS*

#### **1. Whole Grains are Ingredients, As Opposed To Nutrients, But Nutrient Content Analogies Are Relevant.**

GM's petition argues that whole grains are not nutrients and, accordingly, should not be governed by the law and regulations governing nutrient content claims. Rather, GM asserts that whole grains are ingredients, and claims related to whole grains are merely claims descriptive of ingredient content. We agree with GM's legal analysis and conclusion that claims relating to whole grain content should not be subject to the legal restrictions imposed by Congress and FDA on nutrient content claims. However, as a practical matter, since FDA has not provided guidance for making "ingredient content" claims, nutrient content claim analogies offer a useful framework for helping to resolve issues that are key to defining claims relating to whole grain content, such as "daily value" and what constitutes a dietarily meaningful level of this ingredient.

#### **2. The Recommended Daily Consumption Level for Whole Grains Has Been Implicitly "Established."**

The 2005 USDA Dietary Guidelines, which were issued after GM filed its petition, recommend that adult Americans consume at least three "ounce equivalents" of whole grain per day. While USDA did not define "ounce equivalent," the Dietary Guidelines clearly establish that a one-ounce slice of bread is considered a grain "serving."<sup>3</sup> Since there are 16 grams of flour (grain) in a one-ounce slice of bread, it is logical to interpret "ounce equivalent" of grain to mean 16 grams. The benefit of this measurement is that it establishes a constant value for a "serving" of whole grain, regardless of the moisture level of a given food. And, if one "ounce equivalent" equals 16 grams of whole grain, then it follows that the "daily value" recommended by the Dietary Guidelines is 48 grams. This interpretation of the guidelines appears to be consistent throughout the industry.<sup>4</sup>

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<sup>3</sup> See 2005 Dietary Guidelines, p.51; one-ounce of dry cereal and one-half cup cooked rice/pasta/cereal weigh about one-ounce and are considered a serving of whole grain by the Dietary Guidelines.

<sup>4</sup> See Whole Grain Council, How Much is Enough?, available at, <http://www.wholegraincouncil.org/dailyneeds.htm>.

**3. GM's Proposed Claims Thresholds Are Inconsistent With FDA Precedent And Would Discourage Whole Grain Addition to Foods.**

The GM Petition suggests that FDA adopt the following whole grain descriptive claims:

<b>GM PROPOSED DESCRIPTIVE TERM</b>	<b>GM PROPOSED DEFINITION</b>
<ul style="list-style-type: none"><li>• Excellent Source of Whole Grain</li><li>• Rich in Whole Grain</li><li>• High in Whole Grain</li></ul>	Food contains 16 grams or more of whole grain per labeled serving
<ul style="list-style-type: none"><li>• Good Source of Whole Grain</li><li>• Contains Whole Grain</li><li>• Provides Whole Grain</li></ul>	Food contains 8-15 grams of whole grain per labeled serving
<ul style="list-style-type: none"><li>• Made With Whole Grain</li></ul>	Food contains at least 8 grams of whole grain per labeled serving

While the proposed thresholds for making whole grain claims may correspond with GM's offering of Ready-To-Eat cereal products,<sup>5</sup> the comments offer little in the way of a cogent explanation of why these levels are necessary in order for a food to provide a nutritionally meaningful amount of whole grain.

This is not a novel issue for FDA. In promulgating the nutrient content claim regulations in the wake of the enactment of the Nutrition Labeling and Education Act, FDA attempted to strike a balance between setting a level that is nutritionally meaningful, while also attainable by a broad range of foods. FDA settled on 20 percent of the daily value of a nutrient for "excellent source" or "high in" claims, and 10 percent of the daily value for "good source" or "contains" claims. These same levels are equally appropriate for whole grain ingredients, which, like the nutrients that FDA considered in the current NLEA regulations, are available in the diet from a variety of sources.

In striking this balance, FDA lowered the level necessary to make an "excellent source" nutrient content claim from 40% of the daily value to 20% of the daily value when it determined that very few foods would be eligible to meet the 40% threshold, even though they were important sources of nutrients.<sup>6</sup> Again, even though whole grains are not nutrients but ingredients, since FDA has never issued guidance or regulations for "ingredient content" claims

<sup>5</sup> In fact, GM has already reformulated many of its products to meet the proposed levels of whole grains in all Big G® Cereals.

<sup>6</sup> 56 Fed. Reg. at 60442 (Nov. 27, 1991).

we suggest using the levels set forth in the nutrient content claim regulations as a model for establishing "ingredient content" claims. FDA rightly concluded, based on the Institute of Medicine Committee (IOM) report, that a claim is not useful to consumers if it is relevant to too few foods or *only applicable to specially formulated foods*.<sup>7</sup> The threshold level for the claim should "encompass a sufficient number of items in the food supply to ensure that the use of the criterion would encourage consumers to select a varied diet."<sup>8</sup> FDA also emphasized in the preamble "the need to select a diet from a wide variety of foods and to obtain specific nutrients from a variety of foods rather than from a few highly fortified foods or supplements."<sup>9</sup> GM's recommended thresholds would virtually rule out any type of whole grain claims for foods other than cereals, certain breads, and whole grain products such as rice. This would not result in a broader variety of food bearing meaningful information on whole grains, so as to encourage greater consumption.

Consistent with FDA precedent, Kellogg proposes the following whole grain descriptive terms and eligibility thresholds:

KELLOGG PROPOSED DESCRIPTIVE TERM	KELLOGG PROPOSED DEFINITION
<ul style="list-style-type: none"> <li>• Excellent Source of Whole Grain</li> <li>• Rich in Whole Grain</li> <li>• High in Whole Grain</li> </ul>	Food contains 9.6 grams or more of whole grain per labeled serving (at least 20 percent of the "daily value" for whole grain)
<ul style="list-style-type: none"> <li>• Good Source of Whole Grain</li> <li>• Contains Whole Grain</li> <li>• Provides Whole Grain</li> </ul>	Food contains 4.8-9.5 grams of whole grain per labeled serving (at least 10 percent of the "daily value" for whole grain)

Available data show that Americans are currently only consuming approximately one serving of whole grain per day. We believe that establishing reasonable thresholds for making whole grain claims will raise awareness and encourage consumption as consumers see a broader range of foods bearing important whole grain information.

<sup>7</sup> 56 Fed. Reg. at 60442 (Nov. 27, 1991); Committee on Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling, Issues and Directions for the 1990's," Washington, D.C., National Academy Press, 1990.

<sup>8</sup> See *id.*

<sup>9</sup> See *id.*

<sup>9</sup> See *id.*

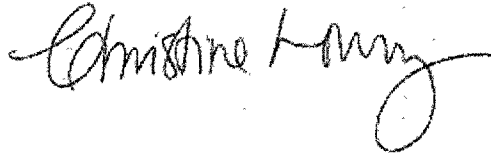
**4. FDA Should Encourage Whole Grain Claims Tied To Dietary Guidelines and the Food Guide Pyramid.**

Since GM filed its petition, the government has issued two major pronouncements encouraging increased consumption of whole grains—the 2005 Dietary Guidelines and the Food Guide Pyramid. We believe that FDA should encourage the dissemination of whole grain information in a manner that is tied to recommendations embodied in the Dietary Guidelines and Food Guide Pyramid. To this end, FDA should affirmatively recognize that 16 grams of whole grain constitutes an “ounce-equivalent” or “serving” of whole grain, as recommended by the Dietary Guidelines. We believe that this would have the practical effect of encouraging communications to consumers that particular foods provide a fraction or multiple of a “serving” of whole grain, so long as the amount of whole grain contained in the food is dietarily meaningful.

*CONCLUSION*

As FDA and USDA focus on encouraging consumers to eat a more nutritious and healthful diet, accurate information in a consumer-friendly format is key. Clearly, providing consumers with useful information about whole grains, as outlined above, will be an important step in this process. We urge FDA to move expeditiously to establish for industry and consumers an appropriate framework for providing this important information.

Respectfully Submitted,

A handwritten signature in cursive script, reading "Christine Lowry". The signature is written in dark ink and is positioned above the printed name and title.

Christine Lowry R.D. M.Sc.  
Vice President Nutrition  
Kellogg Company